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| EXAMINER |
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SIMS, JASON M

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| ART UNIT | PAPER NUMBER |
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1631

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10/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/762,207 | Applicant(s) NADEL ET AL. | |
| | Examiner JASON M. SIMS | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-99 and 134-136 is/are pending in the application.
- 4a) Of the above claim(s) 69,70 and 74-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66-68,71-73,88-99 and 134-136 is/are rejected.
- 7) ☒ Claim(s) 98 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/13/2008 has been entered.

Claims 69-70, 74-87, 98, and 100-133 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventive group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/13/2008.

Applicant has newly added claims 135-136 in the response filed 6/13/2008, which have been acknowledged and entered.

Claims 66-68, 71-73, 88-97, 99 and 134-136 are the current claims hereby under examination.

Claim Objections

Claim 98 is objected to because of the following informalities: Claim 98 has an improper status identifier wherein it should indicate withdrawn as it depends from a non-elected embodiment. Appropriate correction is required.

Art Unit: 1631

The following is a newly added rejection which has been necessitated by amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 66-68, 71-73, 88-99, and 134-136 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 66 and 134 (and all claims dependent therefrom) comprise the amended claim wording "while establishing the timing event, any count of emissions collected from the detection zone being reset upon the establishment of the timing event," which has been deemed as new matter. It is new matter to limit the timing event to be established **while** moving a polymer through a detection zone as support has not been found in the instant specification nor has support been pointed to in the instant specification from applicant. The specification teaches a detection zone is characterized by a zone distance, that a timing event is established, and a polymer is moved through the detection zone at a velocity (see paragraph [0008], but does not teach that the timing event is established while the polymer is moving through the detection zone.

The following is a newly added rejection which has been necessitated by amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 66-68, 71-73, 88-99, and 134-136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 66 and 134 (and all claims dependent therefrom) comprise the claim wording “while establishing the timing event, any count of emissions collected from the detection zone being reset upon the establishment of the timing event,” which has been deemed as vague and indefinite. In particular, it is unclear as to what exactly defines the wording “upon the establishment of the timing event.” For instance, it is unclear if the timing event is established once a signal begins to be detected or if the timing event is established after the signal falls below a particular threshold after it has been detected. In other words it is unclear as to the point at which the emission count is reset. Clarification via clearer claim wording is required.

Claim Rejections - 35 USC § 102

Art Unit: 1631

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 66-68, 71-73, 88-99, and 134-136 are rejected under 35 U.S.C. 102(e) as being anticipated by Chan (P/N 6,355,420).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

The claims are directed to a method of analyzing polymers through high resolution linear analysis. The polymer has first and second specific markers with first and second specific labels at a separation distance; a detection zone is provided where a timing event is established and the polymer is moved through the detection zone at a velocity, whereby the first and second emissions by the first and second labels are detected and proportions of the first and second emissions are calculated and compared to determine the separation distance of the first and second markers.

Art Unit: 1631

Chan teaches claims 66, 88-97, and 134-136 at col. 7 - col. 10. Chan at col. 7 and 8 discusses the analysis of polymers by analyzing a polymer as it is moving through a nanochannel. Chan teach at col. 58, lines 40-42 that the signals detected may be indicative of the distance between units in a polymer. Chan discusses at col. 8, lines 40-48, that the analysis may involve a measurement of the time elapsed between detected signals, which indicates the distance between two units or the length of the polymer. Chan further discusses at col. 8, lines 58-62, at least two units of the polymer are labeled differently so as to produce two different detectable signals. It is inherent that the detected signals of the first unit specific marker and second unit specific marker, which are detected as it passes through the detection signal, correspond to a distance of the detection zone that has been traversed by the label of either the first or the second unit specific marker at the timing events. Chan et al. further teach at col. 58, lines 59-63, that the signals detected are a temporal change, wherein a change fluctuates with respect to the detection of a signal, which reads on a detected signal that is reset after the timing event because of the temporal change indicating that the signal is detected and then set back to normal. Chan discusses at col. 10, lines 57-64, that the polymers may be any type of polymer known in the art, such as a nucleic acid or proteins and that different labels can be used to label different linked units to produce different signals, such as a fluorophore or an electromagnetic label.

Chan teaches at col. 39-col. 44, different fluorescent signal detection schemes which can measure signals from labeled units of a polymer, such as single photon events are detectable. Furthermore, Chan at col. 40, lines 55-58 teaches that efficient

Art Unit: 1631

detection of both intensity and intensity changes, i.e. donor emission in the absence and presence of an acceptor are made, which inherently reads on detecting a proportion of an emission that corresponds to a distance of the detection zone as in claims 135-136. It is inherent because Chan teaches that the emission before the acceptor is present is measurable and the signal of when the acceptor is present is measurable and the difference between the two is calculated. The presence of the acceptor is the time and/or distance the labeled unit is traversing the detection zone, which also establishes the timing event.

Response to arguments:

Applicant's arguments filed 6/13/2008 have been fully considered but they are not persuasive.

Applicant argues that Chan does not teach or suggest determining a proportion of the first or second emission signal that corresponds to a distance of the detection zone traversed by the label of the first or second unit specific marker at the timing event.

Applicant's arguments are not found persuasive as Chan teaches at col. 45, lines 55-67 labeled units of polymers cause signal changes which are unit dependent. Furthermore, Chan teaches at col. 39-col. 44, different fluorescent signal detection schemes which can measure signals from labeled units of a polymer, such as single photon events, are detectable. Furthermore, Chan at col. 40, lines 55-58 teaches that efficient detection of both intensity and intensity changes, i.e. donor emission in the absence and presence of an acceptor are made, which inherently reads on detecting a

Art Unit: 1631

proportion of an emission that corresponds to a distance of the detection zone. It is inherent because Chan teaches that the emission before the acceptor is present is measurable and the signal of when the acceptor is present is measurable and the difference between the two is calculated. The presence of the acceptor is the time and/or distance the labeled unit is traversing the detection zone.

Applicant further argues that claim amendments now clarify that the timing event is not an event that may be superimposed, after the fact, onto the peak of an emission signal to determine when a label is positioned in a central portion of a detection zone and that instead, timing events are established while a polymer is moving through a detection zone.

Applicant's arguments are not found persuasive as they are not commensurate in scope with the claimed invention. The claim amendments do recite amended wording "while establishing the timing event, any count of emissions collected from the detection zone being reset upon the establishment of the timing event." However, the instant wording does not limit the event from being superimposed after the fact, whereas the data from the detector may be sent to memory for further analysis while the additional timing events are being established.

Claims 66-68, 71-73, 88-99, and 134-136 are rejected under 35 U.S.C. 102(e) as being anticipated by Gilmanishin et al. (P/N 6,263,286).

Gilmanishin et al. teaches claims 66-68, 71-73, 88-99, and 134 at the abstract, col. 5, lines 50-62, col. 14, lines 33-48, and col. 15, lines 30-67. Gilmanishin et al., in the

Art Unit: 1631

abstract, discusses determining the spatial separation of specific sites within a polymer. Gilmanishin et al. in the background discusses how polymers can be biological macromolecules such as DNA. Gilmanishin et al. at col. 5, lines 50-62, discusses using a polymer, or extended object, that is similarly labeled with at least two unit-specific markers and passes through a station where the impulses, or signals, are measured and an autocorrelation function is calculated, which reads on a timing event and analyzes the polymer by determining the separation distance between the measured impulses or signals. Therefore, it is inherent that the detected signals of the first unit specific marker and second unit specific marker, which are detected as it passes through the detection signal, corresponds to a distance of the detection zone that has been traversed by the label of either the first or the second unit specific marker at the timing events. Gilmanishin et al. at col. 14, lines 33-48, discusses the calculation of the separation distance between the two unit-specific markers. Gilmanishin et al. at col. 15, lines 30-67, discusses what the different polymers and what the different labels may be. Gilmanishin et al. at col. 4, lines 1-5 teach that fluorescence emitted by the fluorescent molecule, i.e. labeled unit, noticeably exceeds the background, which inherently reads on detecting the proportion of a first or second labeled unit. Gilmanishin et al. further teach that the detected fluorescent bursts and lengths of bursts are related to the time a molecule, i.e. labeled unit, spends within the illuminated volume. Moreover, the detection of the fluorescent bursts from a labeled unit inherently read on a detector that is set to detecting background signals before a labeled unit establishes a timing event, then detects emission bursts from a labeled unit, and goes back to detecting

Art Unit: 1631

background signals after the labeled unit passes, which reads on a detection zone being reset.

Response to arguments:

Applicant's arguments filed 6/13/2008 have been fully considered but they are not persuasive.

Applicant argues that Gilmanshan does not teach or suggest determining a proportion of the first or second emission signal that corresponds to a distance of the detection zone traversed by the label of the first or second unit specific marker at the timing event.

Applicant's arguments are not found persuasive as Gilmanshan at col. 14, lines 40-47, teaches that time dependence is measured for the fluorescence at the wavelength of a labeled end unit and provides information on the velocity of the molecule. A time dependence measurement of the fluorescent signal of a labeled unit inherently is measuring the proportion of the emission signal as the labeled unit is passing through a detection zone and thereby establishing a timing event.

Double Patenting

Response to Arguments

Applicant's arguments, filed 6/13/2008, with respect to the rejection under Double patenting have been fully considered and are persuasive because of applicant's amendments to the claims. Therefore the rejection has been withdrawn.

Claim Rejections - 35 USC § 102(f)

Response to Arguments

Applicant's arguments, filed 6/13/2008, with respect to the rejection under 35 USC 102 (f) have been fully considered and are persuasive because of applicant's amendments to the claims. Therefore the rejection has been withdrawn.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631

Application/Control Number: 10/762,207
Art Unit: 1631

Page 12